



Memorandum

Date: April 5, 2005 0135 5 APR -7 P1:38
From: Humanitarian Device Exemptions (HDE) Staff, ODE, CDRH (HFZ-403)
Subject: HDE Approval Package (H030005)
To: Dockets Management Branch (HFA-305)

Attention:

Jennie C. Butler
Lyle D. Jaffe
Gloria M. Ortega

The following HDE application was recently approved:

HDE Number: H030005
Docket Number: 2005M-0132
Device Name: CoAxia Neuroflo Catheter
Applicant: Coaxco, Inc.

Attached is the following information for this HDE:

Approval Order
Summary of Safety and Probable Benefit
Labeling

If you have any questions, please call me at (301) 594-1307 ext. 209.

Sheila A. Brown

Attachments

2005M-0132

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